

**REMARKS**Final Status of August 13, 2002 Office Action

Applicants respectfully assert that the Office Action mailed August 13, 2002 was improperly made final. The rejection of claims 4, 8-9, and 24-36 under 35 U.S.C. §101 made in the August 13, 2002 Office Action is a new ground of rejection that was not necessitated by Applicant's amendment. Furthermore, in the Office Action mailed January 29, 2002, the Examiner indicated that claims 25-26 are allowed. Now, in the Office Action mailed August 13, 2002, the Examiner has rejected these claims under 35 U.S.C. §101. Clearly, since these claims were not rejected in the January 29, 2002 Office Action and were not amended by Applicants, but are now rejected under 35 U.S.C. §101 and §112, first paragraph, the final rejection is clearly improper with respect to claims 25-26. The final rejection is also improper with respect to all other claims because none of Applicant's amendments necessitated the new ground of rejection.

Rejection of claims 4, 8-9, and 24-36 under 35 USC §101 and §112, first paragraph

The Examiner has rejected claims 4, 8-9, and 24-36 under 35 U.S.C. §101 and §112, first paragraph, as not being supported by either a specific and substantial asserted utility or a well-established utility and, consequently, one skilled in the art would not know how to use the claimed invention.

In making these rejections, the Examiner states that the specification does not specifically disclose the function/activity of the protein of SEQ ID NO:2 or its relationship to any disease, nor does the specification show any enzymatic assays that demonstrate that the protein of SEQ ID NO:2 has enzymatic activity. The Examiner states that it appears that the main utility of the nucleic acids and protein is to carry out further research to identify the biological function and possible diseases associated with the nucleic acids and protein. Thus, the Examiner concludes that the claimed invention has no specific and substantial asserted utility or a well-established utility.

Applicants respectfully assert that, contrary to the Examiner's assertions, the claimed invention is supported by both specific and substantial asserted utilities as well as utilities that are well established in the art.

For example, the Examiner asserts that the specification does not disclose the function/activity of the protein of SEQ ID NO:2. However, it is well known in the art, and specifically stated in the specification, that kinases regulate cell proliferation, differentiation, and signaling process by adding phosphate groups to proteins. Serine/threonine kinases specifically add phosphate groups to serine and threonine residues of substrate proteins.

Additionally, the Examiner asserts that the specification does not disclose the relationship of the protein of SEQ ID NO:2 to any disease. However, it is well known in the art, and specifically stated in the specification, that kinase enzymes play important roles in cancer and other disorders, and therefore it is well established in the art that novel kinases have valuable commercial utilities related to the treatment, diagnosis, and prevention of cancer and other disorders. In addition to cancer, uncontrolled cell signaling has been implicated in a variety of disease conditions including inflammation, arteriosclerosis, and psoriasis. Reversible protein phosphorylation is the main strategy for controlling activities of eukaryotic cells. Reversible phosphorylation is modulated by the counteracting action of kinases, which add phosphate groups, and phosphatases, which remove phosphate groups. Thus, it is well established in the art that novel kinases have valuable and well-established commercial utilities for controlling protein phosphorylation, which in turn enables therapeutic intervention for controlling cancer and other disorders.

Further, the Examiner states that the specification does not show any enzyme assays that demonstrate that the protein of SEQ ID NO:2 has enzymatic activity. However, assays are not needed to satisfy the requirements of 35 U.S.C. §101 and §112, first paragraph. Instead, Applicants have conducted extensive bioinformatic analysis, the methods of which are well established in the art as being accurate and reliable. The results of the analysis, which are provided in the Figures, clearly show that one of ordinary skill in the art would expect the protein of SEQ ID NO:2 to function as a kinase enzyme, even

in the absence of biological assays to validate this activity. For example, Prosite analysis shown on page 2 of Figure 2 indicates the presence of a serine/threonine protein kinase active-site signature at residues 154-166 of SEQ ID NO:2, and Hmmer/Pfam analysis shown on page 4 of Figure 2 further verifies the presence of a eukaryotic protein kinase domain.

Thus, it is clear that the claimed invention in its current form is supported by specific and substantial asserted utilities as well as well-established utilities, and, consequently, one skilled in the art would know how to use the claimed invention. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejections of claims 4, 8-9, and 24-30 under 35 U.S.C. §101 and §112, first paragraph.

**C nclusions**

By way of the above amendments, claims 31-36 have been canceled. As such, claims 4, 8-9, and 24-30 are currently pending.

In view of the above amendments and remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,

CELERA GENOMICS

By: 

Justin D. Karjala

Reg. No. 43,704

Date: October 11, 2002

Celera Genomics Corporation  
45 West Gude Drive, C2-4#20  
Rockville, MD 20850  
Tel: 240-453-3812  
Fax: 240-453-3084